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| 09/171,671      | 05/01/2000  | Martin Quibell       | 179-28              | 8322             |

7590 03/23/2004  
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EXAMINER

WESSENDORF, TERESA D

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1639

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/171,671

Applicant(s)

QUIBELL ET AL.

Examiner

T. D. Wessendorf

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 3-11, 13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election of Group III, claim 12 with the species, cys-protease is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 3-11 and 13-14 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Election was made **without** traverse.

***Status of Claims***

Claims 1-14 are pending

Claims 3-11 and 13-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 1,2 (the linking claims) and 12 are under examination.

***Specification***

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Art Unit: 1639

The disclosure is objected to because of the following informalities: A. There is no Fig. 18 in the Drawings as recited at page 14, lines 20-22 of the specification.

B. The instant specification at page 23, refers to Table II. This table has not been described anywhere in the specification.

Appropriate correction is required.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors (typographical, grammatical and idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

#### ***Information Disclosure Statement***

The listing of references in the specification, pp. 71-72 is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Art Unit: 1639

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35

U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to describe an adequate description of the claimed method of screening for interaction of an active moiety using a library of claim 1 or 12. There is no specific description of a library that contains all types of variations of e.g., first two variable groups or the "unique" sequence of said library in claim 12. Nor a library of numerous undefined variables has been described as recited in claim 1. It is not readily apparent from the description the kinds of variation, either singly or in combinations, for said

Art Unit: 1639

variations and/or the different types of active moiety that interacts therewith. Furthermore, the claimed library can read on all types of linear, cyclic in modified or non-modified form. The specification recites prophetic statements and the belief that the use of a library will identify a component that bind to any active moiety. Example I in the specification provides for a specific description of the specific amino acid that can be contained in the library with the protein kinase as the active moiety. The disclosure at page 68, lines 19-24 however states ".....for the protein tyrosine kinase, the existing libraries may provide some information, although it is envisaged that additional libraries will require to be built. For Ser/Thr kinases, the technology may be adapted by the use of a central Ser or Thr residues as the phosphoacceptor moiety. In addition, technology is being developed with that will allow for the generation of cyclic peptide libraries...."

Sharma states that a major limitation of the soluble library approach is its applicability to high affinity systems. The abundance of each compound in solution can be influenced by the total number of compounds in a library which can affect the biological activity. For

Art Unit: 1639

this reason, a highly active compound in any pool may not in fact be the most potent molecule. Lack of reasonable solubilities of certain members in a library may further influence this phenomenon. In fact, for several libraries the most active peptide was not even identified in the most active library pool. Sharma et al (U.S. 2002/0012948). See also, Blondelle et al (Antimicrobial Agents and Chemotherapy, page 2286). See University of Rochester v. G.D. Searle & Co., 68 USPQ2d 1424 (DC WNY 2003). [Note that claim 1 is rejected to the extent that it is a linking claim. Thus, no utility rejection for the claimed library, per se, as in claim 1 has been made.]

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35

U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 and 12 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1639

A. Claim 12 is not clear as to the meaning of the wells adapted to achieve the stated function. The term "unique" is indefinite as to the qualifying characteristic of its uniqueness. The term "active" is a relative term which renders the claim indefinite. The term "active" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claim 12 is confusing as the base claim recites for a method of screening but no step in either claim is recited. Each of the claims recites limitation more drawn to a compound library.

B. In claim 2 the method of screening is indefinite as it does not recite for any method steps and is confusing as to what is actually being claimed. It is not clear as to the arrangement of the wells in order to adapt for detection of a unique active compound formula. The term "more" is a relative term which renders the claim indefinite. The term "more" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. [It is suggested that at applicants recite ---at least---].



Art Unit: 1639

C. Claim 1 is indefinite as it is unclear as to what is included or excluded from the claims. Furthermore, it is not clear as to the definitions of the different variables B, C, D, Mn and the other variables recited therein for the library.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Deprez (J. Am. Chem. Soc., 1995). [As best as the claims can be interpreted the alternative rejection has

Art Unit: 1639

been applied as the claims are subject to several interpretations.]

Deprez discloses at pages 5405-5406 a method of screening from a pair of orthogonal library a ligand for vasopressin receptor. The method comprises creating two libraries by solid phase procedure. Each library was partitioned into 125 sublibraries of 125 trimers. The first and second libraries were group into five groups. The libraries were partitioned orthogonally in five different groups as shown in Fig. 1b. Each of the library e.g., library A was screened initially in a series of assays. When a positive result was obtained in one assay, library B was screened under the same conditions. This allows a direct identification of the active compound, as the compound is associated with a different set of 124 trimers in library A and B. The activities were determined by the inhibition of binding of radiolabelled vasopressin to renal cells. The prepared libraries require no further deconvolution steps or analysis. Accordingly, the specific process steps of Deprez that employs specific active moiety that interacts with the specific components present in the library anticipates or renders obvious the broad claimed method using broad compounds therein.

Art Unit: 1639

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Houghten et al discloses the generation of synthetic peptide combinatorial libraries.

The elected species, cys-protease, is free of prior art.

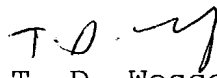
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571)272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1639

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

Tdw  
March 20, 2004